

REMARKS

The remarks are in response to the non-final office action mailed October 5, 2009. Claims 20-23 have been cancelled without prejudice to Applicants' right to prosecute the cancelled subject matter in any divisional, continuation, continuation-in-part or other application. Claims 3, 5-8, 10-11 and 19 have been amended. Claim 3 was amended to correct a grammatical error. The amendments to claims 5-8 are supported in paragraphs [0029]-[0042]. Claims 10-11 and 19 have been amended to better clarify the claimed invention. No new matter is believed to have been introduced.

Applicants acknowledge that claims 1-3 and 9 are free of the prior art and are allowable. Applicants believe that the foregoing amendments and the following remarks place the remaining claims in condition for allowance.

I. CLAIM OBJECTIONS

Claims 3 and 5-8 stand objected to for grammatical errors. Applicants have amended the claims to address these errors. The objection may be withdrawn.

II. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 5-8, 11 and 21-22 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is moot with respect to claims 21 and 22. Applicants respectfully traverse this rejection.

Applicants have amended claims 5-8 to indicate that the "additional" amino acids are at the N- or C- terminus of the peptide of SEQ ID NO:5. This is supported in the specification and is well within the abilities of the skilled person in the art (see, e.g., paragraph [0029]-[0042]). For example, the addition of 1, 2, 3 etc. amino acids at either end of the peptide can be easily accomplished and screened for the ability to bind to an A β 1-40 peptide using the teachings of the specification.

Claim 11 has been amended to eliminate the dependencies from claims 2 and 9 and is therefore clear and definite.

The foregoing rejections may be properly withdrawn.

III. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 5-8, 10-11 and 19-23 stand rejected under 35 U.S.C. §112, first paragraph because the specification, while being enabling for an isolated polypeptide comprising or consisting of the amino acid sequence of SEQ IDNO:4 or 5, allegedly does not reasonably provide enablement for an isolated polypeptide comprising the claimed polypeptide comprising SEQ IDNO:5 and further comprising undefined amino acid sequences or undefined therapeutic/diagnostic compounds, or a hybrid molecule or reagent for treating or diagnosing Alzheimer's disease. Applicants respectfully traverse this rejection.

The Office appears to be trying to limit the Applicants to a single disclosed species of molecule (e.g., biotin) bound to a peptide of the disclosure even where the specification discloses other molecules. Methods of adding amino acids to either the N-terminal or C-terminal end of peptides are commonly performed in the art. Furthermore, methods of conjugating or linking polypeptide and other molecules to peptides are routinely performed in the art. As the Examiner will recognize and as case-law indicates, techniques that are well known in the art need not be described and are preferably omitted from the specification (*In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).). Furthermore, it is not necessary to describe every operable species capable of being conjugated to the peptide of the disclosure. The specification demonstrates that ability, techniques and usefulness of peptide-therapeutic/diagnostic conjugates of the disclosure.

The specification teaches methods to screen such hybrid molecules for activity (e.g., binding to A-beta peptides) using methods and techniques that do not require undue experimentation. Applicants respectfully submit that although the Office alleges that the methods and composition lack enablement, the Office will

recognize that chimeric peptides/polypeptides, fusions and conjugates have been claimed and described for well over a decade and are in-fact commonly performed daily throughout the world.

For at least the foregoing reasons Applicants respectfully submit that the invention is enabled for the scope of the claims to someone of skill in the art. Accordingly, Applicants respectfully request withdrawal of the rejection.

IV. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 5-8, 10-11 and 19-23 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Applicants believe that the remarks above address this rejection. Applicants respectfully submit that the written description requirement was elicited to prevent the introduction of later filed claims that are not supported by the application as-filed. Here the specification supports the language of the claims as-filed. For example, courts have allowed claims added after the original filing of a patent application so long as the added claims were adequately described in the original application's specification. It is possible for the specification to meet the description requirement where the new claim is for broader or different subject matter than that claimed or disclosed in the specification. (*Ralston Purina Co.*, 772 F.2d at 1574-77) In *In re Rasmussen*, the court held that a claim may be broader than the specific embodiment disclosed in a specification. (650 F.2d 1212, 1214 (C.C.P.A. 1981)). The claims at issue in that case, which were directed to the generic step of "adheringly applying" one layer to an adjacent layer, nevertheless were held to be supported by the description because "one skilled in the art who read the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered." (Id. At 1215).

Furthermore, it is recognized that the applicant's specification need not describe the claimed invention *in ipsius verbis* to comply with the written description

requirement. According to the Patent and Trademark Office Board of Patent Appeals and Interferences in *Ex parte Sorenson*, the test for determining whether a claimed invention is adequately described in the specification is whether the originally filed disclosure reasonably conveys to a person having ordinary skill in the art that the applicant had possession of the subject matter later claimed. (*Ex parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (P.T.O. Bd. Pat. App. & Int'f 1987)). In Applicants' application, they have clearly demonstrated possession of a hybrid molecule comprising a peptide sequence of the disclosure (e.g., peptide-biotin). Other molecules can be conjugated or linked to the peptide using well recognized techniques in the art that have been performed for over a decade. In addition, methods of screening for the function of such hybrid molecules are clearly within the possession of the skilled person in the art using the disclosure of the present application.

Furthermore, more recent cases have supported the position that a description of the chemical structure of a protein or polypeptide are not required where the structure of the molecule is recognized in the art. (*Capon v. Eshhar v. Dudas*, 418 F.3d 1349, 1360 (Fed. Cir. 2005)). In *Falkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006) the Federal Circuit held that "[A] requirement that patentees recite known DNA structures, ...would serve no goal of the written description requirement. It would neither enforce the *quid pro quo* between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention....Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification." (*Falkner v. Inglis*, 79 USPQ2d at 1007-8).

In the present case, Applicants have provided specific examples and indicated that other molecules used in therapeutics and diagnostics can be conjugated to the peptides of the disclosure. Again, such methods of conjugation and linking are known in the art and reciting every operable species of molecules that can be linked to the peptide would only add unnecessary bulk to what is clearly demonstrated to be in the possession of the Applicants.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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